PROTECT carotid artery stenting study

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Early results of the PROTECTed Carotid Artery Stenting in Subjects at High Risk for Carotid Endarterectomy (PROTECT) Study were recently presented at the 2009 International Stroke Conference of the American Heart Association (San Diego, Calif, Feb 18-20, 2009).[1]

This study included patients from 34 centers recruited between 2006 and 2008 and assessed a new embolic protection device, Emboshield Pro (Abbott Laboratories, Abbott Park, Ill), used with the Xact stent (Abbott). Study participants were required to be at high risk for endarterectomy (CEA). High-risk criteria included contralateral internal carotid artery (ICA) occlusion, post-CEA restenosis, ejection fraction <35%, and age >80 years. Participants were restricted to those with ≥50% symptomatic ICA stenoses or ≥80% asymptomatic lesions. Investigators reported the early (30-day) results of the first 220 patients.

Most of the patients were men (64%). The mean patient age was 72.5 years, and 29.5% were aged >80 years. Comorbidities included coronary artery disease (71%), previous coronary artery bypass grafting (29%), left ventricular dysfunction (25%), hypertension (89%), dyslipidemia (90%), prior CEA (23%), and contralateral ICA occlusion (13%). The mean degree of lesion stenosis was 73.5% and the mean stenosis length was 18 mm.

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Competition of interest: none.

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Device success (<50% residual stenosis) was achieved in 98.6% of patients. Within 30 days of the procedure, there were three minor strokes, one death, and one myocardial infarction, for a composite rate of stroke or death of 1.8% (95% confidence interval [CI], 0.5-4.6). The composite rate of stroke, death, or myocardial infarction was 2.3% (95% CI, 0.7-5.2), and rate of transient ischemic attack was 3.6%.

The trial investigators concluded that primary outcome event rates were low, and when compared with the SECURITY (Study to Evaluate the Neurosheild Bare Wire Cerebral Protection System and Xact Stent in Patients at High Risk for Carotid Endarterectomy) and ARCHeR (ACCULINK for Revascularization of Carotids in High-Risk Patients) registries, the composite event rates were lower in the PROTECT study. They propose that this may be due to greater experience and improved patient selection.

COMMENTARY

A low rate of periprocedural neurologic events, myocardial infarctions, and deaths was achieved in this study of stenting in high-risk symptomatic and asymptomatic patients. This is commendable, but the applicability to one's practice remains unclear.

High-risk status remains somewhat subjective and variable among the different studies and registries, making comparison difficult. In addition, the advantage of any intervention in high-risk patients remains uncertain with the absence of a medically treated comparative group.

REFERENCE

1. Chaturvedi S, Gray WA, Matsumura J. Safety outcomes from the PROTECT carotid artery stenting multi-center study. Stroke 2009; 40:2.